UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

SUBJECT: Flexibility to Modify CWA Methods - Automated Methods

OFFICE OF WATER

FROM: Richard Reding, Chief
Engineering & Analytical Support Branch, EAD, OST

TO: Quality Assurance Managers
ATP Coordinators
NPDES Coordinators

DATE: April 2, 2007

The Methods Update Rule, published March 12, 2007 (72 FR 11200), added a provision that provides the regulated community with the flexibility to automate analysis by an approved Clean Water Act (CWA) methods without further EPA action. Previously, in a Memorandum (Guidance on the Use of Discrete Analyzers Under EPA Clean Water Act Programs), dated January 27, 2005, Geoffrey Grubbs, Director of the Office of Science and Technology (OST), had provided guidance on the use of discrete analyzer instrumentation for permitting and compliance monitoring under the Clean Water Act. The amended regulations at 40 CFR Part 136.6 (72 FR 11239-40) authorize an analyst to modify an approved test procedure in certain circumstances, provided that the chemistry of the method or the determinative technique is not changed. Further, the regulations explicitly state as follows:

> **Potentially acceptable modifications regardless of current method performance include changes between automated and manual discrete instrumentation** 40 CFR 136.6(b)(1)(i).

Consequently, under this provision, a modification that simply automates an approved CWA method to add a discrete analyzer does not require review as an Alternate Test Procedure (ATP). The automated method becomes like any other method approved under 40 CFR Part 136 that a laboratory chooses to use. So long as the analyst complies with the requirements of section 136.6 (e.g., establishing equivalent performance, documentation), the automated method is an approved method under 40 CFR Part 136.

Thus, laboratories that automate a CWA method will not require an ATP determination letter. To require processing under the ATP procedures of automated (e.g., discrete analyzer) or other method modifications that fall within the scope of 136.6 is not only contrary to section 136.6, but is at odds with the spirit and intent behind the amendment to Part 136. Moreover, it is clearly inconsistent with this Office's desire to reduce the administrative burden associated with implementation of the current ATP program.

We recommend that permitting authorities specify in the NPDES permit that the discharger and its laboratory ensure that approved methods modified to add a discrete analyzer produce results equivalent to those produced by the unmodified method as required in section 136.6(b)(2)(i). To ensure equivalency, we recommend that EPA Regions and permitting authorities use the following items, and the January 27, 2005, memo to evaluate the suitability of a discrete analyzer modification:

Each discrete analyzer developer should:

- Provide a copy of the modified method that shows how each step of the underlying approved method has been modified.
- Provide a copy of the data comparing the modified method performance to the approved method.

Before using the discrete analyzer method the laboratory should demonstrate proficiency by:

- writing a Standard Operating Procedure,
- documenting an initial demonstration of capability
    - verify approved method versus discrete analyzers on seven separate days on the plant effluent,
- using the same reagents, reactions and determinative step as the approved method,
- meeting the quality control (QC) specifications of the method
    - if the reference method does not provide sufficient QC specifications, the targets listed in the December 1996 Streamlining Guide *(applies only to CWA methods)* may be used (http://www.epa.gov/waterscience/methods/guide/flex.html), and
- having the discrete analyzer manufacturer's supporting data.

As with any method, the laboratory maintains documentation of initial and ongoing proficiency with the automated methods.

The purpose of the ATP program is to review (for potential approval) innovative, more effective, or more accurate analytical methods. Our focus is on new chemistries and detectors, or modifications to approved methods that are clearly outside either the scope of the flexibility provided in the underlying approved method, or 40 CFR Part 136.6. Please forward this information and encourage your auditors to allow use of properly modified CWA methods. If you have questions, please contact Lemuel Walker at walker.lemuel@epa.gov.

Thank you for your cooperation. Lem and I look forward to working with our EPA and state partners to improve and streamline the CWA ATP program.

cc Lemuel Walker, CWA ATP Coordinator
Steve Wendelken, SDWA ATP Coordinator
Richard Witt, Office of General Counsel

Attachment – January 27, 2005, Geoff Grubbs Discrete Analyzer memo.

Excerpt from March 12th (72 FR 11240) Methods Update Rule that promulgated 40 CFR 136.6

(6) *QC* means ''quality control.''
(b) *Method Modifications.*
(1) *Allowable Changes.* Except as set forth in paragraph (b) (3) of this section, an analyst may modify an approved test procedure (analytical method) provided that the chemistry of the method or the determinative technique is not changed, and provided that the requirements of paragraph (b) (2) of this section are met.
(i) **Potentially acceptable modifications regardless of current method performance include changes between automated and manual discrete instrumentation;** changes in the calibration range (provided that the modified range covers any relevant regulatory limit); changes in equipment such as using similar equipment from a vendor other than that mentioned in the method (*e.g.*, a purge-and-trap device from OIA rather than Tekmar), changes in equipment operating parameters such as changing the monitoring wavelength of a colorimeter or modifying the temperature program for a specific GC column; changes to chromatographic columns (treated in greater detail in paragraph (d) of this section); and increases in purge-and-trap sample volumes (provided specifications in paragraph (e) of this section are met). The changes are only allowed provided that all the requirements of paragraph (b)(2) of this section are met.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D C 20460

OFFICE OF
WATER

JAN 27 2005

MEMORANDUM

SUBJECT: Guidance on the Use of Discrete Analyzers Under EPA Clean Water Act Programs

FROM: Geoffrey H. Grubbs, Director
Office of Science and Technology

TO: Water Division Directors
Quality Assurance Managers
ATP Coordinators
NPDES Coordinators

We have received some inquiries from several instrument manufacturers about our position on the use of discrete analyzers as an alternative to the use of test procedures (i.e., analytical methods) approved under 40 CFR Part 136. This memorandum provides recommendations on the use of discrete analyzer instrumentation for permitting and compliance monitoring under EPA's Clean Water Act (CWA) programs. This memorandum does not address laboratory certification requirements that states have mandated. The recommendations contained in this memorandum are applicable to the use of discrete analyzers under CWA programs only.

Background

For purposes of this memorandum, a "discrete analyzer" is defined as "an instrument that automates an analysis performed by a method approved at 40 CFR Part 136, and produces results equivalent to results produced by the approved method." As such, discrete analyzers are capable of improving laboratory efficiency and reducing laboratory waste.

In principle, if a method employing a discrete analyzer simply automates the chemistry in the corresponding approved method, then the method employing a discrete analyzer should produce results equivalent to those produced by the approved method. EPA's Office of Science and Technology (OST) has reviewed information submitted by manufacturers, dischargers, and laboratories regarding the application of discrete analyzers in environmental analyses and has determined that discrete analyzers can produce results equivalent to results produced by methods approved at 40 CFR Part 136.

that the laboratory use QC acceptance criteria in the alternate test procedure (ATP) protocol. (see http://www.epa.gov/waterscience/methods/EPA821B98003.pdf).

- Details of the method employing a discrete analyzer should be consistent with details of the approved method including: preservation and holding time requirements (40 CFR Part 136, Table II), interferences, and required QC measures, as specified in the approved method or otherwise required by EPA.

- The discharger and its laboratory should keep documentation on file that demonstrates that the method employing a discrete analyzer provides equivalent results to the approved method. The instrument manufacturer may provide the equivalency demonstration documentation [and may collect it as specified in the ATP protocol or the EPA National Environmental Research Laboratory-Cincinnati (NERL-Ci) side-by-side protocol (http://old.lib.ucdavis.edu/govdoc/EPA/atpnpdes.pdf).] However, the laboratory should also keep on file the results of laboratory performance tests (e.g., MDL data, initial precision and accuracy data) demonstrating that the discrete analyzer is capable of producing results equivalent or superior to results produced by the approved method.

If the discharger and its laboratory meet the above recommendations, then OST believes that a method employing a discrete analyzer is an acceptable version of the approved method and does not require an application and approval through EPA's ATP program at 40 CFR §§ 136.4 and 136.5.

Attached is a checklist of the information that laboratories should maintain on file for use of methods employing a discrete analyzer. If you have questions or comments regarding this memorandum, please contact William Telliard at (202) 566-1061.

cc: Mary T. Smith
Herb Brass
Robin K. Oshiro

Attachment

Recommendations on the Use of Discrete Analyzers

Under the National Pollutant Discharge Elimination System (NPDES) permits program, monitoring must be conducted according to test procedures approved under 40 CFR Part 136 for the analyses of pollutants having approved methods under that part, and according to a test procedure specified in the permit for pollutants with no approved methods [See 40 CFR § 122.44(i)(1)(iv)]. The responsibility for generating acceptable compliance data rests with the discharger and its laboratory. Therefore, the discharger and its laboratory are responsible for demonstrating that the results obtained when employing a discrete analyzer are equivalent to the results produced by the approved method. We recommend that permitting authorities specify in the NPDES permit that the discharger and its laboratory ensure that methods using discrete analyzers produce results equivalent to those produced by the approved methods (see criteria below on equivalency demonstration). To ensure equivalency, we recommend that Regions and permitting authorities use the following items when evaluating a discharger or its laboratory for using a discrete analyzer instrument:

- The discharger or its laboratory should notify the appropriate state regulatory/control authority prior to use of a discrete analyzer instrument and the applicable parameter(s).

- Regions and permitting authorities should allow use of a discrete analyzer only if there is an equivalent method approved at 40 CFR Part 136 and the requester clearly identifies the approved method. All other sample preparation requirements including sample distillation and digestion must be adhered to as stated in 40 CFR Part 136.

- The method employing a discrete analyzer should use the same reagents and chemical reactions as the promulgated method. Any changes, such as use of surfactants or slight pH changes, that do not affect the chemical reaction should be documented and justified.

- Final chemical ratios in the method employing a discrete analyzer that affect the result of the determination should be the same as the ratios in the approved method.

- The discrete analyzer instrument should use the same measurement technology as the approved method (e.g., colorimetric or spectrophotometric).

- The analytical range of the method employing a discrete analyzer should be similar to the analytical range of the approved method and must meet the requirements of the permit.

- The number and range of calibration standards in the method employing a discrete analyzer should be equal to or greater than the number and range of calibration standards in the approved method.

- The precision, recovery, and method detection limit (MDL) obtained with the method employing a discrete analyzer should be equal or superior to the precision, recovery, and MDL in the promulgated method. In cases where the approved method does not contain quality control (QC) acceptance criteria for precision, recovery, and MDL, we recommend

Attachment A

Discrete Analyzers
Equivalency

Use of discrete analyzers for certain of the EPA methods may be used if:

1. The manufacturer provides a written certification that the use of the technology with the manufacturer's accompanying technical notes is equivalent* to the cited EPA method and
2. The following supporting information is provided

Two-Column Comparison:

EPA Reference Method
Scope & Application
    Applicable Range
Method Summary
Equipment
Reagent & Standard Preparation
Final Ratios
Method Performance
    Precision
    MDL
    Accuracy

Technical notes:

Must discuss or cite:
    Acceptability by specific EPA Programs
    Interferences
Safety
    Support and Analytical Equipment and Supplies
    Reagent preparation, storage and handling
    Most recent sample handling and/or preservation requirements
    Quality Control measurements and acceptance criteria
    Calibration and standardization
Sample preparation (digestion, distillation, etc) as required by the cited method or Federal Register
Detailed procedure using the manufacturer's instrument
Data Analysis and Calculations
    Pollution Prevention and Waste Management

Supporting Information:
Typical Calibration Curve, using recommended number of calibration points
Method Detection Limit Study (meeting EPA requirements for number, and concentration level)
Precision and Accuracy Studies (at approximately 10X the MDL)

*equivalent means that the manufacturer's method uses the same reagents (surfactants excluded) as the cited method; the determinative instrumentation, and the final chemical ratios are the same; the range of use and the number and concentration of the recommended calibration standards are equivalent; and the precision, accuracy and method detection limit for the manufacturer's method is equal to or better than the cited method